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Original Article

AI-Driven Automation In eCTD Submissions: Opportunities And Implementation For Indian Pharmaceutical Industry

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ABSTRACT

Artificial Intelligence (AI) is progressively reshaping regulatory affairs in the pharmaceutical sector by enhancing efficiency, precision, and adherence in electronic Common Technical Document (eCTD) submissions. Even though eCTD has established itself as a worldwide benchmark for regulatory submissions, the processes involved in its preparation and lifecycle management continue to be complicated, lengthy, and susceptible to human mistakes because of the vast documentation and manual operations. This assessment examines the impact of AI-powered automation in enhancing eCTD submissions, concentrating on the Indian pharmaceutical sector. Literature from 2020 to 2025 was reviewed to explore the use of AI technologies, such as Machine Learning (ML), Natural Language Processing (NLP), Robotic Process Automation (RPA), and Explainable AI (XAI), in regulatory processes. These technologies facilitate automated document creation, metadata extraction, validation, and compliance oversight, thus improving submission efficiency. Research shows that incorporating AI can cut document processing time by about 35% and lower submission errors by 26–40%, whereas eCTD implementation by itself brings down preparation time by nearly 25%. The shift to eCTD 4.0 enhances structured data management and boosts interoperability, making AI integration easier. Despite these advantages, issues like data privacy worries, absence of regulatory uniformity, and elevated implementation expenses remain, especially in India. In general, automation powered by AI has considerable potential to improve regulatory efficiency and speed up digital transformation in pharmaceutical submissions.

Keywords: AI, Clinical Trial Data, Regulatory filing, Drug Industry. NLP, Machine Learning, India.

INTRODUCTION

The pharmaceutical industry is one of the most regulated sectors globally, requiring extensive documentation to ensure the safety, quality, and effectiveness of medicines. Regulatory submissions are crucial for obtaining marketing authorization, clinical trial approval, and maintaining compliance throughout a product's lifecycle. [1]To standardize submissions across different regions, the International Council for Harmonization (ICH) developed the Common Technical Document (CTD), which was later updated to the Electronic Common Technical Document (eCTD) for digital submissions.[2]

CTD and eCTD dossiers contain detailed information on product quality, manufacturing, non-clinical studies, clinical data, safety, and effectiveness. Traditionally, preparing a dossier involves a lot of manual work, including compiling documents, formatting, validating, cross-referencing, and managing the lifecycle. Growing regulatory demands have made submission management more complicated, resulting in higher workloads, longer timelines, and an increased risk of documentation errors.[2]

Recent advances in digital technologies have changed how pharmaceutical regulatory operations work. Artificial Intelligence (AI), Machine Learning (ML), Natural Language Processing (NLP), and Robotic Process Automation (RPA) are increasingly used to automate tasks like document classification, metadata generation, validation, compliance monitoring, and regulatory intelligence. These technologies improve

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efficiency, lessen manual work, and enhance the quality of submissions.[3]

The launch of eCTD 4.0 has opened up more opportunities for automation within a structured, metadata-driven, and user-friendly submission framework. Its stronger lifecycle management and data handling capabilities make it a good fit for AI-enabled regulatory systems. This review focuses on how AI-driven automation can assist with eCTD submissions, highlighting applications, benefits, challenges, and future prospects, especially in the Indian pharmaceutical industry.[1,3]

1.1 Evolution of CTD and eCTD Systems

The creation of the Common Technical Document (CTD) and its electronic version, eCTD, has greatly improved pharmaceutical regulatory submissions. It has increased global standardization, submission efficiency, and communication between pharmaceutical companies and regulatory bodies. Advances in digital technologies have further sped up the adoption of modern electronic submission standards.[3]

2. COMMON TECHNICAL DOCUMENT (CTD)

The Common Technical Document (CTD) was developed by ICH to establish a standardized format for regulatory submissions across various regions.[4]

2.1 Objectives of CTD

- Standardize regulatory dossier structure
- Reduce duplication of documentation
- Support simultaneous global submissions
- Improve consistency in regulatory review
- Enhance communication between applicants and regulatory authorities

Before the CTD was implemented, companies created different dossier formats for various regulatory agencies. This approach led to increased workloads, higher costs, and slower approvals. The CTD addressed these challenges by providing a globally accepted standardized structure.[4,5]

2.2 Structure of CTD

The CTD consists of five modules:

- **Module 1** – Regional Administrative Information
- **Module 2** – Summaries and Overviews
- **Module 3** – Quality (CMC)
- **Module 4 –** Nonclinical Reports
- **Module 5 –** Clinical Study Reports

2.3 Transition from CTD to eCTD

As pharmaceutical development grew more complex, paper-based CTD submissions posed challenges in document management, version control, and global submissions.[9]

2.3.1 Limitations of Paper-Based CTD

- Extensive manual documentation
- Large physical storage requirements
- Difficulty tracking document revisions
- Increased submission errors
- Longer review timelines

To overcome these limitations, the pharmaceutical industry embraced the Electronic Common Technical Document (eCTD), converting traditional paper dossiers into a structured electronic format.[6,7]

3. ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD):

The Electronic Common Technical Document (eCTD) is an electronic version of the CTD format that uses an XML-based standardized structure for regulatory submissions.[5,9]

3.1 Major Features of eCTD[6]

- Electronic document management
- XML-based framework
- Hyperlinking and bookmarking
- Automated validation checks

- Lifecycle management and version control
- Improved document retrieval

3.2 Benefits of eCTD

- Faster submission preparation and review
- Reduced administrative workload
- Improved traceability and compliance
- Better communication with regulatory agencies
- Reduced paper usage and storage costs [8]

3.3 Evolution of eCTD Versions

The evolution of eCTD from a basic electronic submission format to an advanced digital framework has enhanced submission quality, lifecycle management, traceability, and regulatory efficiency. Modern eCTD systems also support AI-driven automation technologies.[5]

Year	Version	Key Features
2000	CTD	Introduction of harmonized paper-based submission format with 5 standardized modules
2003	eCTD v2.0	Initial transition from paper-based to electronic submissions
2005	eCTD v3.0	Introduction of electronic dossier structure with basic lifecycle management
2008	eCTD v3.2.2	XML backbone, hyperlinking, improved validation, and global adoption
2021	eCTD v4.0	HL7 RPS-based architecture, advanced metadata, interoperability, and enhanced lifecycle management
Present	eCTD 4.0 Adoption	Support for AI integration, automation, structured data exchange, and digital regulatory transformation

Table No. 01: Evolution of CTD and eCTD Systems [5]

3.4 Technical Components of eCTD

3.4.1 XML Backbone

- Central framework for submissions
- Stores document metadata
- Supports automated navigation and validation
- Enables machine-readable submissions

3.4.2 Lifecycle Management

• Tracks document updates throughout the product lifecycle

• Supports replace, append, and delete operations

• Maintains submission history

• Simplifies post-approval changes

3.4.3 Hyperlinks and Bookmarks

• Improve navigation within dossiers

• Provide quick access to related information

• Reduce review time

3.4.4 Validation Mechanisms

• Verify compliance with regulatory requirements

• Identify submission errors

• Improve submission quality and approval rates

The structured architecture of eCTD, especially eCTD 4.0, provides a solid foundation for AI-driven automation by supporting intelligent document processing, compliance monitoring, and workflow automation.[10]

3.5 Limitations of eCTD 3.2.2

- Manual tracking of lifecycle updates
- Complex document change management
- Supports only one-way communication
- Limited flexibility for large dossiers
- Restricted metadata reuse
- Limited compatibility with advanced digital technologies
- Increased workload and potential review delays[11]

Feature	CTD	eCTD 3.2.2	eCTD 4.0
Submission Type	Paper-based	Electronic	Structured Digital
Lifecycle Management	Manual	Basic	Advanced
Metadata Handling	Minimal	Limited	Extensive
Automation Support	Low	Moderate	High
AI Compatibility	Very Low	Moderate	High
Communication	Manual	One-way	Two-way
Validation	Manual	Automated	Intelligent/Advanced
Interoperability	Low	Moderate	High
Content Reuse	Not Supported	Partial	Strong
Regulatory Efficiency	Low	Improved	Highly Efficient

Table No. 02: Comparative Analysis of CTD, eCTD 3.2.2, and eCTD 4.0[10]

3.6 Need for eCTD 4.0

- To provide a more flexible and efficient lifecycle management system.
- To improve metadata handling and structured data exchange.
- To support content reuse and reduce duplication of documents.
- To enhance interoperability across global regulatory agencies.
- To enable better communication and collaboration between stakeholders.
- To support AI, automation, and digital regulatory workflows.
- To improve submission quality, review efficiency, and regulatory compliance.

- To strengthen global harmonization and support future regulatory modernization.[4 -11]

4. eCTD 4.0 AND DIGITAL TRANSFORMATION

eCTD 4.0 is the version of the Electronic Common Technical Document. It was developed by the International Council for Harmonization (ICH) to modernize regulatory submissions. ECTD 4.0 is based on the Health Level Seven (HL7) Regulated Product Submission (RPS) standard.[12] This standard enables data exchange, interoperability and communication between pharmaceutical companies and regulatory authorities.[13]

eCTD 4.0 was introduced to address the limitations of eCTD versions. It supports the increasing demand for digital and globally harmonized regulatory processes.[14]

4.1 Objectives of eCTD 4.0

- To modernize the submission process through a flexible and standardized framework.
- To improve lifecycle management of documents and submission sequences.
- To support metadata for better organization, retrieval and management of regulatory information.
- To enable document reuse across submissions reducing duplication and improving consistency.
- To enhance interoperability between regulatory authorities and information systems.
- To facilitate exchange of regulatory data using internationally accepted standards.
- To support automation, digital. Advanced regulatory review processes.
- To improve submission quality, accuracy and regulatory compliance.
- To promote harmonization of electronic regulatory submissions.
- To provide a foundation for technologies like Artificial Intelligence (AI) machine learning and advanced analytics.

4.2 Key Features of eCTD 4.0 [19]

4.2.1 Harmonized Submission Structure

- It combines Module 1 and ICH content into a single XML-based submission.
- This simplifies submission management and improves consistency across regions.
- It reduces complexity compared to the dual XML structure used in eCTD 3.2.2.

4.2.2 Forward Compatibility

- It allows a seamless transition from eCTD 3.2.2 to eCTD 4.0 without creating an application.
- It maintains existing lifecycle operations, metadata and submission history.
- It supports continuity of activities during migration.

4.2.3 Two-Way Communication

- It enables communication between sponsors and regulatory agencies.
- It supports the exchange of queries, responses and additional information requests.
- This improves collaboration and regulatory review efficiency.

4.2.4 Context of Use (CoU)

- It defines the location and purpose of documents within the submission structure.
- It helps organize content under CTD headings.
- It supports lifecycle management of documents.

4.2.5 Keywords

- They replace metadata used in earlier eCTD versions.
- They provide information related to products, studies, manufacturers and document types.
- They improve document classification and retrieval.

4.2.6 Controlled Vocabularies

- They ensure the use of terms and coded values.
- They promote consistency and interoperability across systems.
- They improve the accuracy of data exchange and validation processes.

4.3 Components of eCTD 4.0[14-19]

4.3.1 XML Schema

- It defines the structure, elements and attributes used in eCTD 4.0 submissions.
- It serves as the backbone of the electronic submission framework.
- It supports automated validation and navigation of submission content.

4.3.2 Object Identifiers (OIDs)

- They are unique identifiers used to define code systems and controlled vocabularies.
- They support standardized classification of regulatory information.
- They facilitate interoperability between different regulatory systems.

4.3.2 Unique Identifiers (UUIDs)

- They provide identification for applications, submissions, documents and other submission elements.
- They ensure tracking and lifecycle management of regulatory content.
- They maintain document identity throughout the submission process.

4.3.3 Code Systems

- They convert coded values into regulatory information.
- They support communication between sponsors and regulatory authorities.
- They improve data consistency and interpretation.

4.3.4 Regional Specifications

- They define region- requirements and business rules.
- They allow customization of submissions according to authority expectations.
- They support regulatory harmonization while maintaining regional compliance.

4.3.5. Folder Structure

- They organize documents within directories and modules.
- They ensure document management and retrieval.
- They support validation, review and lifecycle tracking of submission content.

The advanced features and structured architecture of eCTD 4.0 provide a foundation for digital regulatory transformation. Its standardized data model, lifecycle management capabilities and interoperability support the integration of Artificial Intelligence (AI) automation technologies and intelligent regulatory workflows in regulatory affairs. [19]

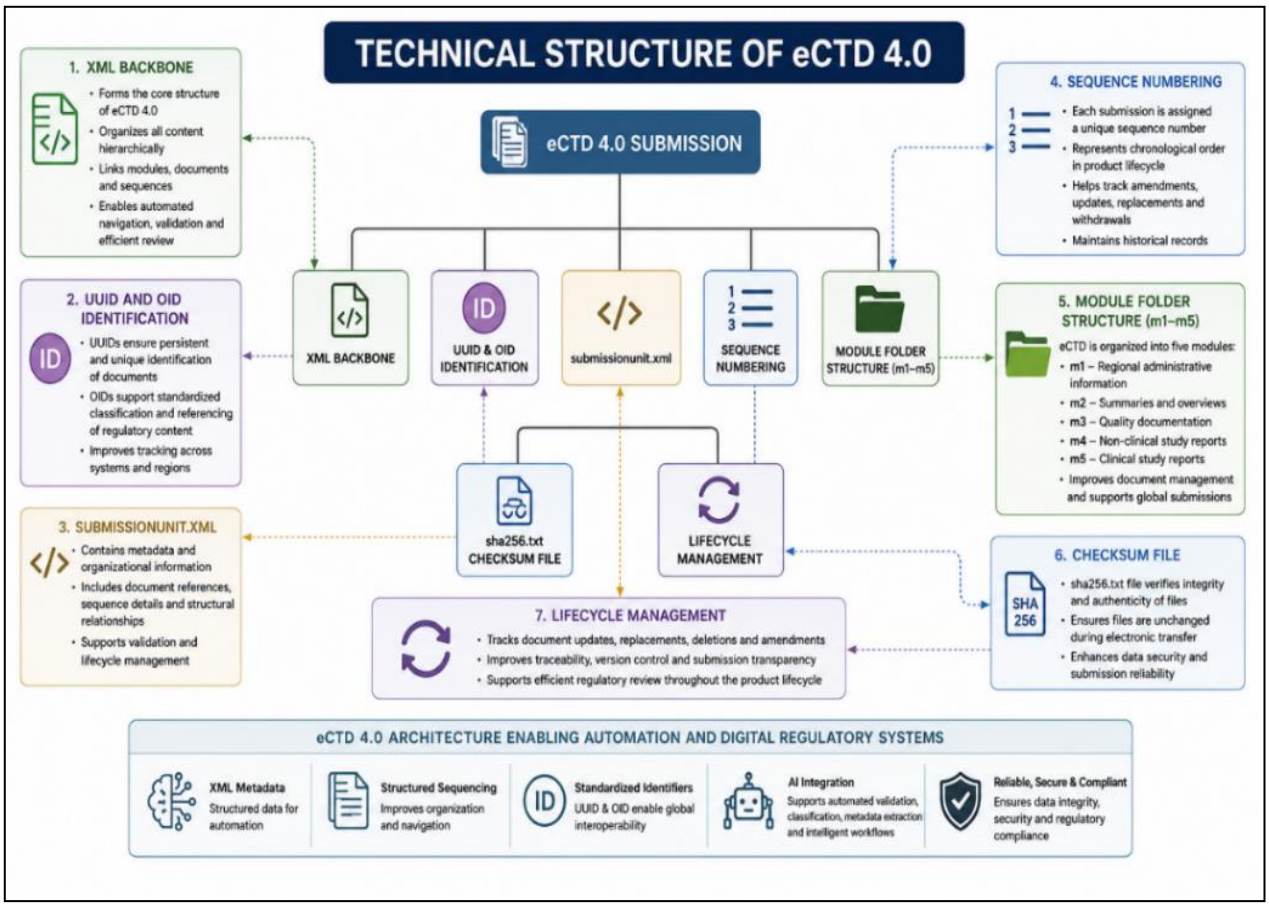

Figure No.05: Technical structure of eCTD 4.0

4.4 Relevance to AI-Driven Regulatory Affairs

The structured and metadata-rich architecture of eCTD 4.0 provides a foundation for implementing Artificial Intelligence (AI) Machine Learning (ML) Natural Language Processing (NLP) and Robotic Process Automation (RPA).[20] These technologies can automate document classification, validation, compliance monitoring and regulatory intelligence activities thereby improving efficiency and reducing effort.[21]

Recent advancements in AI technologies including machine learning (ML) natural language processing (NLP) and robotic process automation (RPA) have created opportunities, for automating regulatory submission workflows.[22] AI-driven systems enable automated document classification, content extraction, validation checks, metadata generation and regulatory intelligence analysis. They have demonstrated that AI-based automation significantly improves compliance, audit readiness and documentation accuracy while reducing manual workload.[24]

AI Technology	Application in eCTD	Benefit
Machine Learning (ML)	Predictive analysis, risk detection	Improved decision making
NLP	Document processing, data extraction	Increased accuracy
RPA	Workflow automation	Faster submission
XAI	Transparent decisions	Regulatory trust

Table No 03: AI Technologies in Regulatory Submissions

Natural Language Processing (NLP) helps manage large volumes of unstructured regulatory text through automated document analysis, content comparison, and information extraction, improving efficiency and consistency in submissions. However, challenges related to data quality and model validation remain.[25]

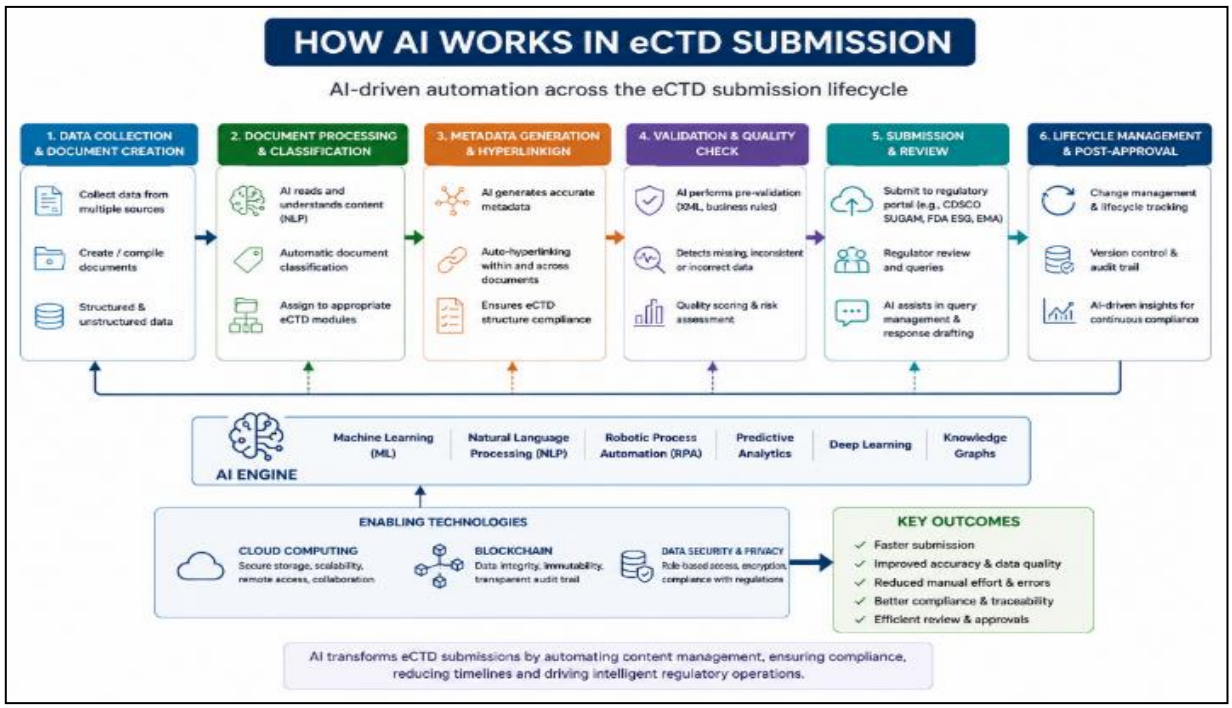

Fig. No. 03: AI driven automation across the eCTD submission lifecycle

eCTD 4.0 is a major advancement in regulatory submissions, using structured content and metadata-driven systems to improve interoperability, lifecycle management, traceability, and automation. It also supports integration with advanced digital technologies.[26]

AI-driven automation improves regulatory workflows but requires transparency, explainability, and ethical implementation. Explainable Artificial Intelligence (XAI) enhances trust, accountability, and regulatory acceptance.[27] AI also supports risk assessment, benefit–risk evaluation, and review processes, improving consistency and efficiency.[28]

Technologies such as Machine Learning (ML), NLP, and Robotic Process Automation (RPA) automate document classification, metadata generation, validation, and lifecycle management in eCTD submissions. Cloud computing and blockchain further improve data security and workflow efficiency.[29]

4.4 Benefits of eCTD 4.0

eCTD 4.0 improves regulatory submissions through better data structure, automation, and communication, enabling faster reviews, reduced redundancy, and improved global interoperability.[28]

4.4.1 Enhanced Lifecycle Management

- Automated tracking of submission updates and version history
- Reduced manual document management[2]

4.4.2 Improved Review Efficiency

- Faster document retrieval and evaluation
- Reduced regulatory queries and quicker approvals

4.4.3 Reduced Redundancy

- Reuse of documents across applications
- Improved consistency and fewer submission errors

4.4.4 Real-Time Two-Way Communication

- Faster interaction between sponsors and regulators

- Improved transparency and query resolution

4.4.5 Content Modularity and Reuse

- Efficient document referencing using OIDs and UUIDs
- Reduced repetitive uploads

4.4.6 Improved Metadata Handling

- Better document classification and tracking
- Supports automation and compliance

4.4.7 Global Harmonization

- Easier cross-regional submissions
- Reduced reformatting requirements

Despite these advantages, the implementation of AI-driven eCTD systems in India is associated with several infrastructural, regulatory, and operational challenges. Addressing these limitations is essential for the effective integration of AI technologies into pharmaceutical regulatory affairs. [2]

Although AI-based technologies enhance efficiency, accuracy, and workflow management in regulatory submissions, human expertise and regulatory oversight remain crucial to ensure reliability, ethical implementation, and compliance with regulatory standards. [6]

4.5 Global Implementation of eCTD 4.0

Pharmaceutical regulation bodies in various key markets are moving towards adopting eCTD 4.0. A number of regulators will mandate the use of eCTD 4.0 for drug submissions in the coming years.[27]

Regulatory Agency	Adoption Status	Expected Timeline	Key Considerations
FDA (USA)	Voluntary eCTD 4.0 submissions initiated	Mandatory adoption expected by 2029	Gradual transition supported by pilot programs
EMA (Europe)	Currently using eCTD 3.2.2	Transition planned by 2027–2028	Focus on harmonization and interoperability
PMDA (Japan)	Active transition and pilot testing	Mandatory adoption targeted by 2026	Strong regulatory preparedness
Health Canada	Expanding pilot implementation	Full implementation planned by 2026	Alignment with ICH guidelines and digital modernization
CDSCO (India)	Pilot implementation through SUGAM portal	Official timeline not finalized	Requires infrastructure development, technical training, and regulatory alignment

Table No. 04: Global eCTD 4.0 Adoption Status

As a result, there is a gradual shift being seen in the adoption of upgraded technology by pharmaceutical companies.[28]

Though considerable progress has been made worldwide in adopting AI-driven regulatory systems, implementation in India's pharmaceutical regulatory system is at an early stage.

Criteria	Traditional CTD/eCTD	AI-based eCTD
Document Creation	Documents created manually	Automatic processing of documents
Verification	Manual validation	Automatic metadata creation
Metadata Generation	Manual metadata creation	Automatic metadata creation
Lifecycle Management	Manual lifecycle tracking	Automated lifecycle monitoring
|Error Probability	Higher chance of error	Lower due to automation
Submission Timeline	Takes more time to process	Quick submission process
Compliance Review	Manual compliance checking	AI-supported compliance monitoring
Operational Efficiency	Moderate efficiency	Improved efficiency and productivity

Table No. 05: Comparative Analysis of Conventional and AI-Enabled eCTD Systems

4.6 Current Status of Digital Adoption in India

India currently uses the CTD format under the New Drugs and Clinical Trials Rules (NDCTR), 2019. The country is slowly moving toward mandatory eCTD implementation through efforts by CDSCO.[27] Many large Indian pharmaceutical companies already use eCTD 3.2.2 when submitting to agencies like the USFDA and EMA. However, the adoption of eCTD 4.0 is still in the early stages.[34] Only a few companies are evaluating or testing the new system. This shows that the digital maturity of regulatory operations in the Indian pharmaceutical industry is still developing.[35]

5. INDIAN PHARMACEUTICAL INDUSTRY PERSPECTIVE

India is one of the largest producers of pharmaceuticals globally. It plays a crucial role in supplying generic medicines, vaccines, and active pharmaceutical ingredients (APIs). [36] The Indian pharmaceutical industry exports its products to highly regulated markets such as the United States, Europe, and Canada, as well as to emerging international regions. As global regulatory requirements shift toward digital submissions, Indian pharmaceutical companies are increasingly using electronic submission methods to stay competitive and meet compliance standards.[37]

5.1 India's Position and Strategic Opportunities

The adoption of artificial intelligence in India's regulatory affairs remains in its early stages, primarily constrained by infrastructure limitations and a lack of standardized data formats.[38] Despite these challenges, initiatives such as the CDSCO SUGAM 2.0 platform indicate a transition in the direction of digital regulatory processes. [39]These developments establish a foundation for AI applications in dossier validation, document classification, and regulatory intelligence.[40]

Entity	Platform / System	Application	Implementation Status	Key Outcome
FDA (USA)	ELSA & KASA	AI-assisted dossier review	Operational	Faster reviews and improved data integrity
EMA (Europe)	IRIS Platform	Validation and document routing	Operational	Improved efficiency and transparency
CDSCO (India)	SUGAM 2.0	Digital submissions and planned AI integration	Pilot Stage	Initial step toward automation
Pfizer	Veeva Vault RIM + AI	Automated dossier compilation	Active Use	Improved CTD consistency
Sun Pharma	AI-based RIM System	Document management and validation	Pilot Stage	Improved internal efficiency
Dr. Reddy's Laboratories	AI-based document QC	Metadata correction and validation	Pilot Stage	Reduced manual verification time

Table No 04: Global and Indian Adoption Landscape of AI-Driven Regulatory Platforms[41]

The integration of Natural Language Processing, Machine Learning, and Robotic Process Automation into regulatory workflows will likely depend on coordination between regulatory bodies, pharmaceutical manufacturers, and technology providers. Aligning domestic practices with the frameworks established by the FDA and EMA may facilitate the development of a more standardized digital regulatory environment in India.[40]

Table 4 outlines the current implementation status of AI-driven regulatory platforms within global and domestic contexts.

This comparison shows that while regulatory agencies in developed markets have transitioned to operational AI-supported systems, the Indian regulatory landscape is currently characterized by pilot programs and developmental initiatives. Even so, the development of technological transformation inside the pharma sector indicates a definite course toward greater artificial intelligence-powered automation within Indian regulatory compliance.[41]

Barrier	Description	Impact
High Cost	Expensive AI software and infrastructure	Limits adoption
Skilled Workforce Shortage	Lack of AI and eCTD experts	Reduces efficiency
Poor Digital Infrastructure	Dependence on traditional systems	Slows automation
Data Security Concerns	Sensitive regulatory data risks	Compliance issues

Limited Regulatory Guidelines	Few CDSCO AI regulations	Implementation uncertainty
Interoperability Issues	Difficulty integrating systems	Workflow inefficiency
Resistance to Change	Hesitation in adopting new technology	Delays automation
Validation Challenges	Need for continuous AI validation	Affects regulatory acceptance
Limited eCTD 4.0 Awareness	Slow transition from older systems	Delays modernization
Manual Documentation Dependence	Continued use of manual processes	Increases errors and delays

Table No.05: Barriers to AI-Driven eCTD Implementation in India

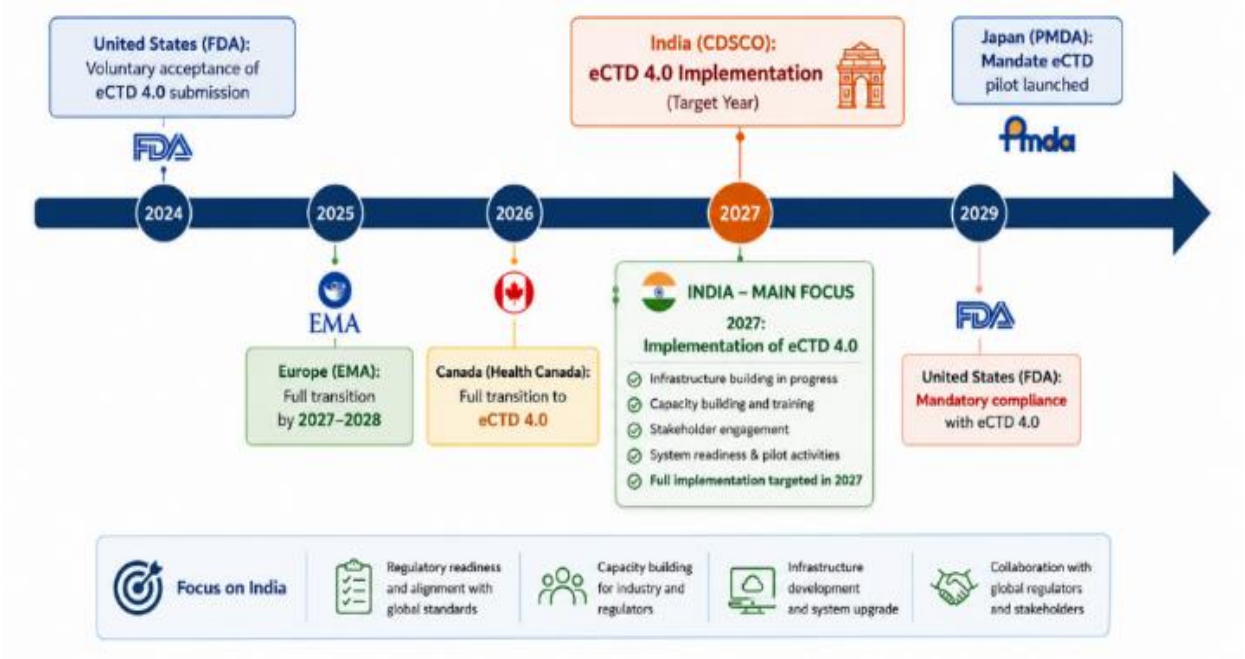

Figure No. 06: Timeline for implantation of eCTD 4.0[11]

5.2 Future Prospects of Artificial Intelligence in Regulatory Affairs

The function of Artificial Intelligence (AI) in pharmaceutical regulatory matters is anticipated to grow considerably with the continuous progress of digital technologies. New systems like AI-driven dossier management platforms, predictive regulatory analytics, cloud-based regulatory solutions, and smart document processing tools could modernize conventional regulatory operations and enhance overall workflow efficiency.[42]

Prospective AI applications might enable automatic document categorization, metadata creation, compliance evaluation, lifecycle monitoring, and regulatory insights. Technologies such as Machine Learning (ML) and Natural Language Processing (NLP) can aid in examining extensive amounts of regulatory data, spotting possible compliance concerns, and facilitating quicker and more uniform decision-making procedures.[43]

The adoption of eCTD 4.0 alongside AI technologies is expected to boost submission quality, improve traceability, shorten review timelines, and reinforce global regulatory alignment. Moreover, sophisticated digital technologies like cloud computing, blockchain systems, and organized content management solutions could enhance transparency,

interoperability, and secure data sharing in regulatory frameworks.[44]

With the ongoing evolution of pharmaceutical regulatory systems towards digital transformation, AI-supported regulatory operations are anticipated to assume a more significant role in contemporary submission management. Additionally, implementing explainable AI and organized digital workflows could enhance regulatory confidence, uniformity, and acceptance of AI-driven procedures in pharmaceutical regulatory affairs.[45]

6. KEY FINDINGS

- Artificial Intelligence supports improved efficiency and accuracy in eCTD submission processes.
- Technologies such as NLP and ML assist in automated document review and validation activities.
- eCTD 4.0 promotes structured, interoperable, and digitally optimized regulatory submissions.
- AI-assisted systems help reduce repetitive manual tasks and improve workflow coordination.
- India is gradually moving toward digital regulatory transformation through initiatives such as the CDSCO SUGAM platform.
- Challenges including regulatory harmonization, infrastructure readiness, validation standards, and workforce training continue to influence implementation.

6.1 Research Gap

Existing literature has widely explored the role of Artificial Intelligence (AI) in pharmaceutical regulatory operations; however, comparatively fewer studies have examined its practical application in automating electronic Common Technical Document (eCTD) submissions, particularly in the context of the Indian pharmaceutical sector. Areas such as implementation readiness, regulatory alignment, infrastructure limitations, explainable AI practices, and availability of trained professionals still require deeper investigation. In view of these gaps, the present review focuses on understanding the emerging role of AI in eCTD submissions, along with its applications, benefits, limitations, and future potential in pharmaceutical regulatory affairs.

7. AIM AND OBJECTIVES:

7.1 Aim: AI-Driven Automation in eCTD Submissions: Opportunities and Implementation for Indian Pharmaceutical Industry

7.2 Objective:

1. To study the role of Artificial Intelligence (AI) and automation technologies in eCTD submission systems.
2. To compare CTD, eCTD 3.2.2, and eCTD 4.0 with respect to automation, lifecycle management, and regulatory efficiency.
3. To evaluate the applications of AI technologies such as Machine Learning (ML), Natural Language Processing (NLP), and Robotic Process Automation (RPA) in pharmaceutical regulatory submissions.
4. To identify the opportunities and benefits of AI-driven eCTD systems in the Indian pharmaceutical industry.
5. To analyse the challenges and implementation barriers associated with adoption of AI-driven eCTD systems and eCTD 4.0 in India

8. MATERIALS AND METHODS

8.1 Research Design and Study Type

This study employs a systematic review framework to examine the integration of artificial intelligence within the electronic Common Technical Document submission process in the pharmaceutical industry. The research is non-experimental and descriptive, prioritizing the synthesis of secondary data to assess current practices and technological trends. An analytical approach is used to evaluate findings across multiple studies, while a comparative component contrasts traditional manual workflows with automated systems.

8.2 Sources of Data

Data were collected from established academic databases and regulatory repositories, including PubMed, Google Scholar, ScienceDirect, and the official portals of the United States Food and Drug Administration, the European Medicines Agency, and the Central Drugs Standard Control Organization.

8.3 Data Collection and Selection Criteria

The literature search targeted publications released between 2020 and 2025. Identification of relevant material was conducted using specific keywords such as artificial intelligence in regulatory affairs, eCTD automation, and pharmaceutical submissions. Articles were selected based on their technical relevance, source credibility, and the availability of comprehensive data. Selection was limited to expert-reviewed, English-written publications and sector reports centered on regulation processes. Conversely, the study excluded materials published prior to 2020, non-peer-reviewed sources, and research unrelated to pharmaceutical regulatory processes.

8.4 Data Analysis Method

The collected information was analyzed through qualitative and comparative methods. Findings were categorized into thematic areas, including specific AI technologies, implementation tools, operational benefits, and existing challenges. This categorization allowed for the identification of broader industry trends and the assessment of automation efficiency.

8.5 Comparative Regulatory Analysis

A focused comparison of regulatory frameworks from international agencies and the Indian regulatory authority was performed. This analysis evaluated regional differences in submission requirements, the maturity of digital adoption, and the formal acceptance of AI-driven methodologies.

8.6 Ethical Considerations and Limitations

As the research is based entirely on publicly available secondary data, it did not involve human or animal subjects. Standard academic practices for citation and attribution were followed to ensure research integrity. Study limitations include a reliance on existing literature and restricted access to proprietary industry data. Additionally, the rapid evolution of AI technologies and varying levels of regulatory acceptance across different jurisdictions may affect the long-term applicability of the findings.

8.7 Expected Outcomes and Case Study Analysis

The study intends to identify the primary AI technologies currently utilized in regulatory submissions and to evaluate their specific impact on the Indian pharmaceutical sector. To contextualize these findings, the research incorporates an analysis of selected case studies from published literature. These cases serve to illustrate practical implementation, performance improvements, and the technical hurdles encountered during the adoption of automated systems.

CONCLUSION

The transition from conventional Common Technical Document (CTD) systems to electronic Common Technical Document (eCTD) platforms has significantly improved the efficiency and standardization of pharmaceutical regulatory submissions. The emergence of eCTD 4.0 has further strengthened digital regulatory operations through structured content management, advanced metadata handling, interoperability, and improved lifecycle management. These advancements have created a strong foundation for the integration of Artificial Intelligence (AI) and automation technologies in regulatory affairs.

This review highlights the growing role of AI technologies such as Machine Learning (ML), Natural Language Processing (NLP), and Robotic Process Automation (RPA) in transforming eCTD submission processes. AI-driven systems support automated document classification, metadata generation, validation, compliance monitoring, regulatory intelligence, and workflow management, thereby reducing manual effort, minimizing errors, and improving submission quality and review efficiency. In addition, digital tools including Electronic Document Management Systems (EDMS), Regulatory Information Management (RIM) systems, cloud-based platforms, and blockchain technologies further enhance data management, traceability, and operational efficiency.

Despite these advantages, several challenges continue to limit the widespread implementation of AI-driven regulatory automation, particularly in the Indian pharmaceutical industry. Major barriers include inadequate digital infrastructure, high implementation costs, limited regulatory harmonization, data privacy concerns, lack of skilled professionals, and the need for transparent and explainable AI systems. Regulatory acceptance, ethical governance, and robust validation frameworks remain essential for sustainable adoption.

Overall, AI-driven automation has the potential to reshape pharmaceutical regulatory submissions into more efficient, accurate, and data-driven processes. Continued advancements in digital technologies, stronger regulatory frameworks, global harmonization initiatives, and increased industry preparedness are expected to accelerate the adoption of AI-enabled eCTD systems in the future. India, through initiatives such as the CDSCO SUGAM platform and ongoing digital transformation efforts, has significant opportunities to strengthen its regulatory ecosystem and align with evolving global regulatory standards.

The gradual adoption of AI-enabled eCTD systems reflects a broader transition from traditional document-centred regulatory practices toward more data-oriented and digitally integrated regulatory management.

CONFLICTS OF INTEREST:

The authors declare no conflict of interest. This review is based on publicly available regulatory and scientific literature, and no financial or personal relationships have influenced its preparation or conclusions

REFERENCES

1. Pawar VT, Jadhav SP, Bhamare MS, Mahajan SK. Regulatory affairs in pharmaceutical industry. Asian J Pharm Res. 2026;16(1):1-5.
2. Khanderao GJ, Kubde JA, Hatwar PR, Bakal RL, Karule VG. A review on role of drug regulatory affairs in pharma industry. Int J Pharm Sci Drug Anal. 2025;5(1):192-200.
3. Wagh S, Waghmare SU, Narode P, Shelke P, Borhade V, Kawar R. Regulatory affairs: global perspectives. Int J Pharm Sci. 2024;2(6):1052-1067.
4. Salunkhe P, Nagrale S. Electronic common technical document (eCTD): structure, submission process and regulatory updates. Int J Drug Regul Aff. 2026;14(1):42-50.
5. Dagade S, Chaudhari B. Global harmonization of CTD and eCTD. Int J Pharm Sci. 2026;4(4):1191-1202.
6. Mahaparale S, Desai B. CTD and eCTD implementation overview. World J Pharm Res. 2018;7(7):201-215.
7. Ahammad N, Reddy N, Nagabhushanam MV, Ramakrishna B. Challenges in CTD/eCTD submissions for USFDA and Canada. J Drug Deliv Ther. 2019;9(4 Suppl):673-679.
8. Chaudhari SP, Telrandhe SG, Adhav V, Taktode A. eCTD submission in Europe: regulatory requirements and best practices. Int J Res Anal Rev. 2023;10(3):29-35.
9. Sudesamithiran N. Next generation eCTD review. Int J Drug Regul Aff. 2023;11(4):67-73.
10. Nagar K, Choudhary M, Yadav B, Rahi S, Upadhayay A. Transition to eCTD 4.0. Int J Drug Regul Aff. 2025;13(3):77-84.
11. Venna SR. Optimising global eCTD submissions: harmonisation challenges. Indo Am J Pharm Biol Sci. 2020;18(1):13-18.
12. Boopathi LK, Raja N. AI and machine learning in regulatory affairs. Int J Drug Regul Aff. 2024;12(4):102-110.
13. Amarlapudi E, Akhil P, Divya D, Gremya B, Devayani T. Artificial intelligence and machine learning in revolutionizing pharmaceutical regulatory affairs. Int J Pharm Sci. 2025;3(4):1986-1993.
14. Ananthan S. AI in pharmaceutical regulatory affairs and MSL activities. Int J Drug Regul Aff. 2025;13(4):52-56.
15. Fu L, Jia G, Liu Z, et al. AI applications in drug regulation: global perspective. Acta Pharm Sin B. 2025;15(1):1-14.
16. Muppalla A, Maddi BD, Maddi NV. AI in regulatory compliance. Int J Drug Regul Aff. 2025;13(2):73-80.
17. Jagtap S, Ali SS. AI for regulatory dossier automation. World J Pharm Res. 2026;15(8):23-35.

18. Shaikh AN, Syed SA. Reinventing drug development and regulatory affairs through artificial intelligence. Int J Drug Regul Aff. 2026;14(1):71-77.
19. Bhatt SS, Parmar R. AI in eCTD submission and review. Int J Creat Res Thoughts. 2026;14(3).
20. Kulkov I. AI in pharmaceutical business transformation. Technol Soc. 2021;66:101629.
21. Pawar HB, Neelanshu, Bhat GM, Srikanth A, Muragundi PM. Challenges of using AI-based NLP tools in regulatory documentation. J Appl Pharm Sci. 2025.
22. Shah MB. AI-driven metadata management. Int J Adv Res Electr Electron Instrum Eng. 2019;8(7):2009.
23. Modalavalasa G. AI-driven data governance. PSPC. 2025;52(1):3.
24. Chandrasekaran K, Pramod Kumar TM, Balamuralidhara V. Regulatory automation tools overview. Int J Drug Regul Aff. 2024;12(1):36-39.
25. Venna SR. Regulatory operations in the digital age: optimizing eCTD workflows with data analytics. Indo Am J Pharm Biol Sci. 2019;17(2):20.
26. Venna SR. Intelligent metadata-driven automation for eCTD 4.0 lifecycle management using explainable artificial intelligence. SSRN. 2025.
27. Mane A, Nagrale S. Global regulatory frameworks (USFDA, EMA, CDSCO). Int J Drug Regul Aff. 2026;14(1):33-41.
28. International Council for Harmonisation. CTD guideline M4. Geneva: ICH; 2004.
29. International Council for Harmonisation. M8 eCTD implementation package. Geneva: ICH; 2022.
30. US Food and Drug Administration. eCTD submission specifications guidance. Silver Spring: FDA; 2022.
31. US Food and Drug Administration. Electronic submission format guidance. Silver Spring: FDA; 2024.
32. European Medicines Agency. Submission roadmap and eCTD requirements. Amsterdam: EMA; 2024.
33. Health Canada. eCTD regulatory guidance. Ottawa: Health Canada; 2023.
34. Central Drugs Standard Control Organization. eCTD and SUGAM portal guidance. New Delhi: CDSCO; 2024.
35. Ahmed S. eCTD 4.0 implementation including understanding of regional differences and benefits. IQVIA; 2023.
36. Kimta A, Dogra R. AI in Indian pharmaceutical sector. Int J Nov Res Dev. 2024;9(4).
37. PharmaRegulatory.in. CDSCO eCTD pilot program India roadmap [Internet]. 2025 [cited 2026 Mar 15]. Available from: https://pharmaregulatory.in
38. PharmaRegulatory.in. AI in eCTD compilation and review [Internet]. 2025 [cited 2026 Mar 15]. Available from: https://pharmaregulatory.in
39. PharmaRegulatory.in. Regulatory case studies and best practices [Internet]. 2025 [cited 2026 Mar 15]. Available from: https://pharmaregulatory.in
40. Kivo. Everything you need to know about eCTD 4.0 [Internet]. 2025 [cited 2026 Mar 15]. Available from: https://kivo.io
41. Nagar K, Rahi S, Isfaq M. A study on identifying gaps in traditional regulatory dossier processes and the role of artificial intelligence in streamlining submission workflows. World J Pharm Sci Res. 2026;5(1):27-39.
42. Bhavsar D. eCTD adoption trends and regulatory impact. Sarcouncil J Med Ser. 2024;9.
43. Bhavsar DJ. Strategic project management in regulatory affairs. Int Res J Adv Sci Hub. 2025;7(7):630-636.
44. Pawar KS. Regulatory submission readiness using eCTD metrics. J Regul Aff Qual Assur. 2025;1(1):27.
45. Raj RK, Pattanaik P, Roy H. The dynamics of global pharma regulatory affairs system. Indo Am J Pharm Biol Sci.

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